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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/767,251

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Gerry R. Boss

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FENWICK & WEST LLP
SILICON VALLEY CENTER
801 CALIFORNIA STREET
MOUNTAIN VIEW, CA 94041

EXAMINER

YU, MELANIE J

ART UNIT

PAPER NUMBER

1641

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/767,251	Applicant(s) BOSS ET AL.	
	Examiner MELANIE YU	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 26-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 26-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed 16 November 2009 have been entered and considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 27 depends from claim 1 and recites "a plurality of beads", which is also recited in claim 1. It is unclear whether the plurality of beads recited in claim 1 is the same plurality of beads recited in claim 27. It is further unclear whether the step of contacting the heated beads with the inner wall and partially melting the inner wall recited in claim 27 are the same steps as recited in claim 1 or whether additional contacting and partially melting steps are required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-5, 11, 32 and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polansky (US 2003/0068616) in view of Glad (US 6,156,550) further in view of Wolfbeis et al. (US 4,965,087).

Polansky teaches a method comprising:

coating an inner wall of a test tube with a capture reagent for a macromolecule of interest (par. 1009);

incubating the capture reagent with a solution containing the macromolecule under conditions to allow binding of the macromolecule to the binding partner (antigens exposed to antibodies under conditions that promote binding which indicates incubation, par. 583);

washing the capture reagent with the bound macromolecule with a wash buffer to remove unbound material while maintaining binding of the macromolecule to the binding pair (par. 579 and 583); and

eluting the macromolecule from the binding partner (par. 579 and 583).

Polansky fails to teach partially melting an inner wall of a test tube and coating the inner wall of the test tube with a plurality of beads and coating the beads with a capture reagent.

Glad teaches a substrate having a capture reagent coated with a defined quantity of beads, wherein the beads are coated with a capture reagent of the macromolecules

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of interest (col. 3, lines 3-53), In order to provide a denser packing of particles on a substrate.

Wolfbeis et al. teach partially melting a substrate to immobilize beads permanently within the layer (col. 5, lines 44-56 and col. 6, lines 56-60), in order to provide a rough and reactive sensor surface.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to coat the inner surface of the test tube of Polansky, with beads as taught by Glad, in order to provide a higher surface area for contact with a sample and allow for an increased number of attached capture reagents. It would have further been obvious to one having ordinary skill in the art to immobilize the particles on the inner wall of the substrate as taught by Polansky in view of Glad et al., by partially melting the wall to contain the particles as taught by Wolfbeis et al., in order to provide an attachment that has good stability and high reactivity.

With respect to claims 2-4, Glad teaches the beads being glass (col. 3, line 48), polymer (col. 3, line 49) or agarose (col.4, lines 26-27).

With respect to claim 5, Glad teaches the binding partner attached to the beads by at least one linker molecule (NHS-activated agarose beads, col. 5, lines 4-15).

Regarding claim 11, Polansky teaches a linker molecule being protein A (par. 579).

Regarding claim 32, Polansky teaches a test tube that comprises a polymeric material (par. 1009).

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With respect to claim 34, Glad teaches a substrate that is polystyrene (col. 3, lines 1-11).

With respect to claims 35-37, Polansky teaches the macromolecule being a protein or polynucleotide (par. 583 and 862).

2. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polansky (US 2003/0068616) in view of Glad (US 6,156,550) further in view of Wolfbeis et al. (US 4,965,087), as applied to claim 1, and further in view of Orth et al. (US 2003/0153010).

Polansky in view of Glad further in view of Wolfbeis et al. teach a NHS linker, but do not specifically teach a linker molecule of aminopropyltriethoxysaline.

Orth et al. teach a layered substrate comprising a layer of aminopropyltriethoxysaline followed by a layer of NHS (par. 5), in order to bind photoactivatable biotin to the substrate.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include on the substrate of Polansky in view of Glad further in view of Wolfbeis et al., a layer of aminopropyltriethoxysaline on the substrate under the layer of NHS as taught by Orth et al., in order to form a single self assembled monolayer on the substrate that easily binds NHS.

3. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polansky (US 2003/0068616) in view of Glad (US 6,156,550) further in view of Wolfbeis et al. (US 4,965,087), as applied to claim 1, and further in view of Stimpson et al. (US 5,599,668).

Polansky in view of Glad further in view of Wolfbeis et al. teach a NHS linker, but do not specifically teach a linker molecule of cyanogen bromide.

Stimpson et al. teach a linker being either NHS or cyanogen bromide (col. 17, lines 37-37), in order to provide a covalent attachment

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the NHS linker of Polansky in view of Glad further in view of Wolfbeis et al., with a cyanogen bromide linker as taught by Stimpson et al. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent linking technique and since the same expected linking effect would have been obtained. The use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the economics and availability of components.

4. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polansky (US 2003/0068616) in view of Glad (US 6,156,550) further in view of Wolfbeis et al. (US 4,965,087), as applied to claim 1, further in view of Zhang (US 2003/0046717).

Polansky in view of Glad further in view of Wolfbeis et al. teach a NHS linker, but do not specifically teach a linker molecule of dimethyl suberimidate.

Zhang teaches a chemical cross linker of either an NHS ester or DMS, which is dimethyl suberimidate (par. 365), in order to provide conjugation of a polypeptide.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the NHS linker of Polansky in view of Glad further in view of Wolfbeis et al., with a dimethyl suberimidate linker as taught by Zhang. One having ordinary skill in the art would have been motivated to make such a change

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as a mere alternative and functionally equivalent linking technique and since the same expected linking effect would have been obtained. The use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the economics and availability of components.

5. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polansky (US 2003/0068616) in view of Glad (US 6,156,550) further in view of Wolfbeis et al. (US 4,965,087), as applied to claim 1, further in view of Liu et al. (US 2004/0014101).

Polansky in view of Glad further in view of Wolfbeis et al. teach a NHS linker attaching a capture molecule to a bead, but fail to teach the linker molecule being an antibody.

Liu et al. teach an antibody linker (par. 43) to immobilize a nucleic acid strand on a substrate.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the NHS linker taught by Polansky in view of Glad further in view of Wolfbeis et al. with an antibody linker as taught by Liu et al. because Polansky in view of Glad further in view of Wolfbeis et al. are generic with respect to the type of linker that may be used and one having ordinary skill would have known to use the appropriate linker based on the capture molecule to be immobilized.

6. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polansky (US 2003/0068616) in view of Glad (US 6,156,550) further in view of Wolfbeis et al. (US 4,965,087), as applied to claim 1, further in view of LaMotte (US 5,296,347).

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Polansky in view of Glad further in view of Wolfbeis et al. teach washing a test tube, but fail to teach removing the wash buffer by inversion of the tube.

LaMotte teaches removal of a wash buffer by inversion of a test tube (col. 19, lines 31-37) while assay components are still immobilized to the side of the test tube (col. 19, lines 4-59), in order to remove the wash buffer from the test tubes.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to remove the wash buffer from the test tubes of Polansky in view of Glad further in view of Wolfbeis et al., by inversion of the test tube as taught by LaMotte, in order to provide thorough and adequate removal of unbound material by washing.

7. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polansky (US 2003/0068616) in view of Glad (US 6,156,550) further in view of Wolfbeis et al. (US 4,965,087), as applied to claim 1, further in view of Schall et al. (US 6,699,677).

Polansky in view of Glad further in view of Wolfbeis et al., as described above in the rejection of claim 1, teach the method recited in claim 26, including determining the number of capture molecules released from the receptors (spectrophotometric analysis provides the number of molecules eluted from the test tubes, par. 579), but fail to teach the binding partner being a guanine nucleotide binding protein.

Schall et al. teach an immobilized guanine nucleotide binding protein (G-protein; col. 12, lines 10-30), in order to interrogate the cell expressing the CCR1 intracellular domain.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to use as the binding protein in the method of Polansky in view of Glad further in view of Wolfbeis et al., a guanine nucleotide binding protein because Polansky in view of Glad further in view of Wolfbeis et al. describe numerous types of receptors that may be immobilized to the substrate and one would be motivated to use the appropriate ligands for the detection of the desired analyte.

8. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polansky (US 2003/0068616) in view of Glad (US 6,156,550) further in view of Wolfbeis et al. (US 4,965,087), as applied to claim 1, further in view of Hendriks (US 4,251,616).

Polansky in view of Glad further in view of Wolfbeis et al. teach a step of heating to immobilize particles in a substrate, but differ from the instant claims in failing to specifically teach heating a plurality of beads to a temperature to melt the substrate, contacting the heated beads with the substrate and partially melting the inner wall of the tube using the heated beads.

Hendriks teaches a method of immobilizing particles in a substrate comprising the steps of: heating a plurality of beads to a temperature to partially melt the substrate (col. 6, lines 64-65); contacting the heated beads with the substrate (col. 6, lines 65-68) and partially melting the substrate using the beads (col. 6, lines 65-68), in order to pattern particles on a substrate. When combined with Polansky and Glad, one having ordinary skill in the art would have recognized that the substrate to which the beads are immobilized is the inner wall of the tube.

Therefore it would have been obvious to one having ordinary skill in the art at the

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time the invention was made to include in the method of Polansky in view of Glad further in view of Wolfbeis et al., heating particles to contact with and partially melt the substrate as taught by Hendriks, in order to provide particles that are easily embedded in the substrate.

9. Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polansky (US 2003/0068616) in view of Glad (US 6,156,550) further in view of Wolfbeis et al. (US 4,965,087), as applied to claim 1, further in view of Leach et al. (US 5,470,609).

Polansky in view of Glad further in view of Wolfbeis et al. teach heating a substrate to contain particles, but differ from the instant claims by failing to specifically teach the heat source specifically being a heat gun or infrared irradiation.

Leach et al. teach that conventional heating sources are an infrared lamp, which includes a filament, and heat gun (col. 4, lines 37-42), in order to heat to specific temperatures.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the lamp or laser heat source in the method taught by Polansky in view of Glad further in view of Wolfbeis et al., a heat gun or infrared lamp as taught by Leach et al. because Wolfbeis et al. is generic with respect to the type of heat source that can be incorporated into the device and one would be motivated to use a heat source that is appropriate for heating substrates.

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10. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polansky (US 2003/0068616) in view of Glad (US 6,156,550) further in view of Wolfbeis et al. (US 4,965,087), as applied to claim 1, further in view of Sivaraja (US 6,569,619).

Polansky in view of Glad further in view of Wolfbeis et al. teach a substrate being a test tube, but differ from the instant claims by failing to specifically teach the tube being a microcentrifuge tube.

Sivaraja teaches a substrate being either a test tube or a microcentrifuge tube (col. 14, lines 35-52), in order to provide a solid support or substrate for a complex to form.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to use as tube in the method of Polansky in view of Glad further in view of Wolfbeis et al., a microcentrifuge tube as taught by Sivaraja. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent structural form and since the same expected test tube function would have been maintained. The use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the economics and availability of components.

11. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polansky (US 2003/0068616) in view of Glad (US 6,156,550) further in view of Wolfbeis et al. (US 4,965,087), as applied to claim 1, further in view of Neumann et al. (US 4,366,242).

Polansky in view of Glad further in view of Wolfbeis et al. teach a substrate being a test tube and polystyrene, but differ from the instant claims by failing to specifically teach the material being polypropylene.

Neumann et al. teach a test tube that is made from either polystyrene or polypropylene (col. 3, lines 54-59), in order to provide a water insoluble carrier.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to use as the test tube material in the method of Polansky in view of Glad further in view of Wolfbeis et al., polypropylene as taught by Neumann et al. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent material and since the same expected test tube would have been obtained. The use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the economics and availability of components.

Response to Arguments

12. Applicant's arguments with respect to claims 1-12 and 26-37 have been considered but are moot in view of the new ground(s) of rejection. The previous rejections of the claims have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Wolfbeis et al. teaching melting a substrate to immobilized particles therein.

Conclusion

13. No claims are allowed.

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14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE YU whose telephone number is (571)272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Yu/
Primary Examiner, Art Unit 1641